

MAY 12 2005

**BASIS™ Spinal System  
Summary of Safety and Effectiveness  
May 2005**

**I. Company: Medtronic Sofamor Danek, Inc. USA  
1800 Pyramid Place  
Memphis, TN 38132  
(901) 396-3133**

**Contact: Richard W. Treharne, PhD  
Senior Vice President Regulatory Affairs**

**II. Proposed Proprietary Trade Name: BASIS™ Spinal System**

**III. Classification Name(s)/Product Code(s):  
Classification Name: Spinal Intervertebral Body Fixation Orthosis  
(per 21 CFR Section 888.3060)  
Product Codes: KWQ**

**IV. Product Description**

The BASIS™ Spinal System components included in this submission consist of screws, bolts, nuts and plates as well as ancillary instrument sets. The BASIS™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The BASIS™ Spinal System implant components are made from titanium alloy. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog for further information about warranties and limitations of liability. **Never use stainless steel and titanium implant components in the same construct.**

## V. Indications

### *BASIS<sup>TM</sup> Cervical Plates*

The BASIS<sup>TM</sup> anterior cervical plates are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

### *BASIS<sup>TM</sup> Thoracic/Lumbar Plates*

The BASIS<sup>TM</sup> anterior Thoracic and Lumbar plates are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

### *BASIS<sup>TM</sup> Components*

When used as an anterolateral thoracic/lumbar, or anterior cervical system, BASIS<sup>TM</sup> components are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

## VI. Substantial Equivalence

Documentation was provided which demonstrated the BASIS<sup>TM</sup> Spinal System to be substantially equivalent to the following systems: SYNTHES<sup>®</sup> Cervical Vertebrae Plates (K792352), SYNTHES<sup>®</sup> Spinal Implant System (K802462), ORION<sup>®</sup> Anterior Cervical Plate System (K973854), ZPLATE-ATL<sup>TM</sup> Anterior Fixation System and ZPLATE-ATL<sup>TM</sup> Anterior Fixation System ZPLATE-II (K922543 and K990603) and the VANTAGE<sup>TM</sup> Anterior Fixation System Plate (K023797).



MAY 12 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Richard W. Treharne, PhD  
Senior Vice President, Regulatory Affairs  
Medtronic Sofamor Danek  
1800 Pyramid Place  
Memphis, Tennessee 38132

Re: K051039

Trade/Device Name: BASIS<sup>TM</sup> Spinal System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: KWQ  
Dated: April 22, 2005  
Received: April 25, 2005

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

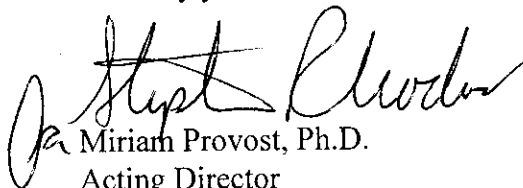
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over the typed name.

Miriam Provost, Ph.D.

Acting Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known):

Device Name: BASIS™ Spinal SystemIndications For Use*BASIS™ Cervical Plates*

The BASIS™ anterior cervical plates are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

*BASIS™ Thoracic/Lumbar Plates*

The BASIS™ anterior Thoracic and Lumbar plates are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

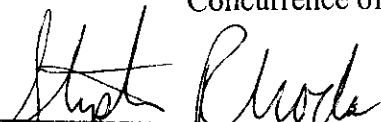
*BASIS™ Components*

When used as an anterolateral thoracic/lumbar, or anterior cervical system, BASIS™ components are intended for the following indications: (1) spinal stenosis, (2) spondylolisthesis, (3) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

Prescription Use X  
(Part 21 CFR 801 Subpart D)AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)**Division of General, Restorative,  
and Neurological Devices**510(k) Number K051037

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